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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,783	10/02/2000	William J. McBride	018733/0997	1348

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EXAMINER

WESSENDORF, TERESA D

ART UNIT PAPER NUMBER

1627

DATE MAILED: 07/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/676,783

Applicant(s)
McBride et al

Examiner
T. Wessendorf

Art Unit
1627



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/10/02
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-44 is/are pending in the application.
- 4a) Of the above, claim(s) 24 (species) is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

1. Applicant's election with traverse of Group I in Paper No. 8 is acknowledged. The traversal is on the ground(s) that it is improper to separate methods of use into distinct groups and that there is no basis in MPEP for such a restriction. This is not found persuasive because the restriction has been merely grouped into separate Groups however, it is evident from the groupings that restriction was done on the different diseases (species) encompassed by the single method claim. [Note that the restriction between the non-elected Groups VI and VII are withdrawn since it is considered that this is one invention. Should a divisional application be filed as a result of this restriction, the two Groups would be rejoin.]
2. The requirement is still deemed proper and is therefore made FINAL.
3. Claims to the non-elected disease species are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

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4. The disclosure is objected to because of the following informalities: at page 28, line 27 to page 9, line 22, some of the recited sequences are repeated. For example, Seq. ID. 2, line 4 has the same structure as Seq. ID. 2, line 14. Applicants should check for other sequences to make sure there are no duplicates of the same sequence.

Appropriate correction is required.

5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 24-40 and 42-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide a written description of the method by which a human patient is treated of a tumor. The specification merely provides a general statement that the disclosed compound is capable of treating a tumor disease. The specification' example, which is alleged to provide guidance or direction for the practice of the claimed invention, merely presents a general description as to the assay method of the binding effect of the compound to breast cancer cells, without any results even for the binding effect. It is not readily apparent from the general description of the binding assay method whether correlation has been made to the treatment or even diagnosis of the disease. As stated above, it is not clear from the statement whether in fact there is even a binding effect of the compound. A claim to a treatment method especially of a disease as complex and as incompletely characterize as any tumor should set forth a description of the treatment effect to a host even not necessarily, humans as claimed, especially in view of applicants' assertion that the radiometal binding-moiety compound being administered is "novel".

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claims 24-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. A). Claim 24 is confusing in that it covers two statutory subject matter i.e., method of using and method of making the radiolabeled peptide.

B). It is not clear whether the administration of the radiolabeled peptide "together" with the carrier is as a unit or two separate components, especially in the absence of positive recitation in the specification.

C). The term "lower" is a relative term. It is suggested that applicants recite the number of carbon atoms contained therein e.g., C1-C6 as recited in the specification. The term has been vaguely defined in the art which covers different number (range) of carbons. Likewise, the aryl as C6-C12; cycloalkyl as C3-C6. The term "substituted" is indefinite as to the kind, number and position of each of the substituents present therein, especially in the absence of positive definition in the specification.

D). It is not clear whether the compound administered is in protected or non-protected form. The claimed "a protecting group that can be removed under the conditions of peptide synthesis" relates to method of making and not using the compound.

E). The process step "then contacting said solution with a radionuclide and recovering the radiolabeled peptide" is a process of making, which is inconsistent with the preceding process of use.

F). Claim 44 recitation of a protein broadens claim 42 recitation of a peptide, especially since the specification does not disclose a protein containing radiometal-binding moiety but only the small length amino acid residues (oligopeptide).

G). Claim 41 contains sequences that are duplicative. For example, Seq. ID. 2 having the same structure is recited twice.

Claims 24-44 are free of prior art.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Each of the Flanagan et al, Griffiths et al and Govindan et al (5,772,981 and 5,746,996) references relates to a radionuclide-binding moiety useful in a method of treating e.g., tumors.

Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If

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applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


T. Wessendorf

Primary Examiner

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